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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,887	03/31/2001	Sanjay Kumar	KUM-108 US	7559

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EXAMINER	
SAKELARIS, SALLY A	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/823,887	KUMAR ET AL.	
	Examiner	Art Unit	
	Sally A. Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/20/2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-14,30-34 and 40-42* is/are pending in the application.

4a) Of the above claim(s) *9-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-34 and 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8, 15-29, and 35-39 have been canceled, claims 9-14 have been withdrawn from consideration, and claims 40-42 are newly added. Claims 30-34 and 40-42 are pending. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

Specification

Applicant should note that the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

35 U.S.C. 101/112 Utility Rejections

35 U.S.C. 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf]

> "Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is

credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

> Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. ' 101. This analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.
>
> "Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

See also the MPEP at 2107 - 2107.02.

> The following is a quotation of the first paragraph of 35 U.S.C. 112:
>
> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 30-34 and new claims 40-42 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either a substantial or a well established utility.

Applicants have asserted on The claimed nucleic acid is not supported by a specific asserted utility because the disclosed use of the nucleic acid is not specific and is generally applicable to any nucleic acid. The specification states that the nucleic acids may be useful as a

hybridization probe to complementary molecules in other plants using probe design methods, cloning methods, and clone selection as is well known in the art. The specification teaches on page 22 that an embodiment of the invention includes using the novel sequences as probes to look for the sequences of nucleotides in other plants, animal, and/or microbial systems and the like. The novel sequence of SEQ ID NO: 1 is taught to be used to clone full-length cDNA, genomic DNA, promoter and regulatory sequences. Furthermore, an embodiment of modulating winter dormancy using the novel genes in the plants after transferring these genes using the techniques such as ballistic mediated transformation. These are non-specific uses that are applicable to nucleic acids in general and not particular or specific to the nucleic acid being claimed.

Further, the claimed nucleic acid is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acids have asserted or identified specific and substantial utilities. The research contemplated by applicants to characterize potential full length genes and furthermore their protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid such that another non-asserted utility would be well established for the compounds.

Response to Arguments:

Applicant's arguments filed 6/20/2005 have been fully considered but they are not persuasive. First, applicant's assert that the claimed sequence can specifically be used to modulate winter dormancy. However, this has not been disclosed by applicant. The specification provides no evidence that SEQ ID NO:1 is capable of modulating dormancy in the tea bush plant or in any plant for that matter. The specification only asserts that a probe for the 3' end of the 31.2 gene hybridizes to a sequence expressed only in non-dormant and forced non-dormant samples(Figure 20). It is a non-specific property of an oligonucleotide being able to hybridize to another nucleotide. There is no disclosure that this probe and SEQ ID NO: 1 are the same or share any sequence characteristics that would explain a retention of a similar function in a different experiment such as the one applicant is suggesting they have already done i.e. transformation and subsequent expression studies. There is no disclosure that SEQ ID NO: 1 could cause non-dormancy if transformed into a tea bush plant or tree but instead only properties generally applicable to any nucleic acid are disclosed. In response to applicant's arguments regarding the alleged, specific utility had by their nucleic acid(pages 4-5 of response)it would appear that applicant is arguing properties of their invention that were not disclosed in the specification as originally filed nor were they well-established by the art.

While chart 2 of the background section has been noted, it is not clear what association is had between them and applicant's data which is a detection method with the 3' end of the 31.2 gene.

While applicant maintains that their invention has a substantial utility in modulating dormancy in plants, this is not convincing to the office. Applicant has not showed what their substantial utility is, i.e., what is it that they do when they modulate dormancy in plants? While the applicant asserts that "modulating plant dormancy has been and will continue to be a key issue in agriculture system[s]" and that while "the claimed DNA sequence may not be the sole means to regulate winter dormancy in plants, it is nevertheless a substantial use for the claimed sequence" it again should be noted by applicant that they are arguing properties(the ability to modulate winter dormancy) that have not been disclosed in the application as originally filed nor are they well-established.

While applicant's including references are noted, applicant is reminded that they are both post date filing art, and cannot be relied upon to illustrate the alleged, "well-established" nature of the invention at the time of filing.

While applicant's arguments and related references regarding differential gene expression are noted, it is unclear how this relates to applicant's data that is void of any expression study involving a transformed SEQ ID NO:1 construct into a plant and the subsequent, putative ability to confer some sort of dormancy phenotype.

This asserted utility seems to suggest transformation of plants with SEQ ID NO:1 to confer a non-dormant phenotype. However, no "method of modulating dormancy" such as this or any others is present in the specification. As the present specification provides only that the detection of SEQ ID NO:1 in non-dormant, dormant, and forced(GA3), samples is practiced by the applicant and not the over-expression/repression/transformation of SEQ ID NO:1 that is directly responsible for the entry into non-dormancy, but instead the application of a plant growth regulator, gibberrellic acid(GA3) that is responsible for the buds entry into non-dormancy, SEQ ID NO:1 does not represent a substantial utility. SEQ ID NO:1 may or may not be present in non-dormant/dormant buds, but to assert that its mere detection implies its responsibility for the transition requires further research to substantiate.

No evidence has been provided that reveals that SEQ ID NO:1 is solely responsible for modulating winter dormancy in tea plants, as a multitude of other events that occur when GA3 is administered could account for the modulation. While the applicant suggests that "the office provide evidence to the contrary" regarding the assertion of a specific, substantial, and well-established utility, "The applicant is reminded that once a *prima facie* showing of no specific and substantial utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing evidence in the form of a declaration under 37 CFR 1.132 or a patent or printed publication that rebuts the basis or logic of the *prima facie* showing"(Federal Register/Vol.66, No.4, January 5, 2001, *Guidelines for Examination of applications for compliance with the utility requirement).*

In addition, further experimentation is necessary to attribute a utility to the claimed nucleic acid encoding this protein. *See Brenner v. Manson*, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical

compound whose sole "utility" consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 30-34 and new claims 40-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Claims 30-34 and 40-42 are drawn to a product that can be used in a non-descript method of modulating dormancy in non-dormant apical buds of the first tea bush or tree. However, as will be further discussed, there is no support in the specification and prior art for SEQ ID NO: 1's ability in modulating dormancy. The invention is a` class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The unpredictability of the art and the state of the prior art

The present specification provides only that the detection of SEQ ID NO:1 in non-dormant, dormant, and forced(GA3), samples is practiced by the applicant and not the over-expression/repression/transformation of SEQ ID NO:1 that is directly responsible for the entry into non-dormancy, but instead the application of a plant growth regulator, gibberellic acid(GA3) that is responsible for the buds entry into non-dormancy, SEQ ID NO:1 is not shown to directly cause dormancy. In fact, SEQ ID NO:1 may or may not even be present in non-dormant/dormant buds, and to assert that its mere detection implies its responsibility for the transition requires further research to substantiate. No evidence has been provided that reveals that SEQ ID NO:1 is solely responsible for modulating winter dormancy in tea plants, as a multitude of other events that occur when GA3 is administered could account for the modulation. There is great unpredictability in the practice of a method that is not even disclosed that will be able to modulate dormancy when SEQ ID NO:1 is used.

The prior art further confirms the unpredictability of this area. White et al.(Plant Physiology, April 2000) teach methods involving gibberellins and seed development in Maize but assert that the stage of development is an important variable in the study of signaling during

a plants maturation. While the present inventors give no indication of development stages, White et al. assert that "maize embryos at successive stages of development show distinctive germination patterns on hormone free medium"(pg. 1091). Furthermore though that, "treatment with GA synthesis inhibitors also decreased both the rate of germination and the fraction of embryos that germinate, but these effects were found to be contingent on developmental stage"(Pg. 1091). As a result, not only since the specification does not disclose what they intend to do to modulate dormancy, but also because they do not at all comtemplate how they will do this, considering the many variables that exist, taking the above developmental stages as just as an example of a variable that would be encountered, it is highly unpredictable how to use this invention without a utility.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied to apply this technology to in vivo methods, including the stability of the polynucleotide complex in plants, the distribution of the nucleic acids in different parts of the plant, the optimum mode of effective administration and the pharmocokinetics of administration. For a polynucleotide complex, one must also consider (a) the ability of the oligonucleotide to specifically bind the target gene; (b) formation of a stable triple complex between the oligonucleotide and the target gene (note that modification of the oligonucleotide may interfere with its ability to form stable hydrogen bonds, etc.; (c) uptake of the oligonucleotide by the cell; (d) solubility of the oligonucleotide of the cell, and other such constraints. The time table necessary to achieve efficacious administration of effective oligonucleotides, effective temperatures and pH conditions would require a very large quantity of experimentation for in vivo applications. This would require years of inventive effort, with

each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Working Examples

The specification has no working examples of a method that modulates dormancy.

Guidance in the Specification.

The specification provides no evidence that SEQ ID NO:1 is capable of modulating dormancy in the tea bush plant or in any plant for that matter. The specification only asserts that a probe for the 3' end of the 31.2 gene hybridizes to a sequence expressed only in non-dormant and forced non-dormant samples(Figure 20). There is no disclosure that this probe and SEQ ID NO: 1 are the same or share any sequence characteristics that would explain a retention of a similar function. There is further no disclosure that SEQ ID NO: 1 could cause non-dormancy if transformed into a tea bush plant or tree. Even if, arguendo, the applicant provides a utility for SEQ ID NO: 1 they have yet to provide an explanation of how to use this sequence to achieve that utility.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, in a highly unpredictable art where a nucleic acid complex's effects in vivo depend upon numerous known and unknown parameters such as the metabolism specific to the target DNA, potential secondary structure, oligonucleotide length and oligonucleotide chemical composition for triplex DNA, the factor of unpredictability weighs

heavily in favor of undue experimentation. Further, the prior art and the specification provides insufficient guidance to overcome the art recognized problems in the use of SEQ ID NO: 1 to modulate dormancy. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Response to Arguments:

Applicant's arguments filed 6/20/2005 have been fully considered but they are not persuasive.

Applicant's assertion in their recent 6/20/2005 filing that "an enablement rejection based on lack of utility should not be imposed if a well-established utility is asserted". However, as is noted above in response to the utility rejection, no such well-established utility is noted. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. Applicant's assertions regarding [0052] and [0053] on page 7 of their response are noted, these passages do not enable the prophetic invention presently being argued.

THE FOLLOWING ARE NEW REJECTIONS NECESSITATED BY APPLICANT'S ADDITION OF NEW CLAIMS

3. Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 1. Claim 40 is directed to encompass a polynucleotide sequence comprising a polynucleotide sequence having at least 80 per cent homology to the polynucleotide sequence of SEQ ID NO:1. The specification provides no explicit definition of "homology" referring to any required sequence similarity. Furthermore, there is no assertion as to which portion of that which is 80% homologous, is required to maintain applicant's presently asserted, prophetic function. As no other structural information is present, the genus of structures being claimed is quite large. The sequences comprising sequences with an 80 per cent homology to SEQ ID NO: 1 includes splice variants and larger clones, genomic DNA, etc, that minimally has some sort of 80% homology to SEQ ID NO: 1. Reading these claims as broadly as they are written, one could interpret that the entire Camellia sinensis L. (O.) Kuntze genome be encompassed in claims with only minimally including a an 80% homology somewhere. A review of the full content of the specification indicates that the sequence of SEQ ID NO:1 and all aforementioned variations, are essential to the operation and function of the claimed invention. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or

simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The named ORF is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for isolating and characterizing cDNA sequences from *E. grandis*, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe *E. grandis* cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the specification does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute *E. grandis* cDNA appears in the application. Accordingly, the specification does not provide a written description of the invention of claims 1, 4, and 6-15.

Therefore, none of the sequences encompassed by the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

4. Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

In the instantly rejected claims, the new limitation of "80 per cent homology" in claim 40 appears to represent new matter. No specific basis for this limitation was identified in the specification, nor did a review of the specification by the examiner find any basis for the limitation. Since no basis has been identified, the claims are rejected as incorporating new matter.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A. Sakelaris whose telephone number is 571-272-0748. The examiner can normally be reached on M-Fri, 9-6:30 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sally Sakelaris
9/6/2005

W. Gary Jones
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